Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0706271	(X3) Date Survey Completed 11/03/2021
Name of Provider or Supplier Marquette University Medical Clinic	**Street Address, City, State** 540 N 16th Street, Milwaukee, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory proficiency testing records from 2020 and 2021 and interview with testing personnel, both testing personnel in the laboratory performed six of six hematology cell identification challenges while patient differential cell identifications are routinely performed by one person. Findings include: 1. Review of laboratory proficiency testing records from event three in 2021 showed two sets of hematology cell identification results, both results were dated September 29, 2021, staff C initialed one set of results, staff D initialed the second set. The event forms showed the results were due by October 1, 2021. 2. Interview with testing personnel (staff C) on November 3, 2021 at 10:15 AM confirmed the hematology cell identification portion of the proficiency testing events in 2020 and 2021 were performed by both testing personnel while patient differential cell identifications were routinely performed by one person.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel,

	the laboratory did not retain records of the lot number and expiration dates of stain used for hematology differential testing during 2020 or 2021. Findings include: 1. Review of laboratory records showed no evidence of records of the lot number or expiration dates of the Camco Quik Stain used for hematology differential testing. 2. Interview with testing personnel (staff C) on November 3, 2021 at 10:45 AM confirmed records of the Camco Quik Stain were not retained.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel, the laboratory has not documented the reactivity of the Camco Quik Stain on days of use for hematology differential testing in 2020 or 2021. Findings include: 1. Review of laboratory records from 2020 and 2021 showed no evidence of documentation showing the Camco Quik Stain was evaluated for intended reactivity each day of use. 2. Interview with testing personnel (staff C) on November 3, 2021 at 10:45 AM confirmed testing personnel have not documented the reactivity of the Camco Quik Stain each day of use for hematology differential staining.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory refrigerator, review of temperature records and interview with testing personnel, the laboratory director did not ensure maintenance of the quality assessment program to ensure the refrigerator maintained acceptable temperatures from January through November 2021. Findings include: 1. Observation of the laboratory refrigerator on November 3, 2021 at 10:35 AM revealed a digital Fahrenheit (F) thermometer with a recording chart in the refrigerator. The digital thermometer showed 44 degrees F, the chart recording showed 52 degrees. Further observation revealed the laboratory stored Coulter hematology controls in the refrigerator; the control label showed the required temperature range for storage is two to eight degrees Celsius (C). 2. Review of manual temperature logs in the laboratory showed the acceptable temperature range for the refrigerator was 38 to 48 degrees F. (38 F equals 3.3 C, 48 F equals 8.9 C) 3. Review of temperature charts from January 6, 2021 through October 27, 2021 showed temperatures between 50 and 54 F. The charts included notations that all temperatures were within range. 4. Interview with

	testing personnel (staff C) on November 3, 2021 at 10:30 AM confirmed the temperature on the chart did not match the digital temperature reading. Further interview confirmed the quality assessment program was not maintained to ensure storage temperatures were acceptable.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on surveyor review of competence evaluation records from 2019 to 2021 and interview with testing personnel, the technical consultant did not document the performance of two of two mid-level providers responsible for moderate complexity provider performed microscopy (PPM) testing annually. Findings include: 1. Review of competence evaluation records from 2019 through 2021 showed no evidence of evaluation of staff A and staff B, two mid-level providers that perform vaginal wet mount and potassium hydroxide testing. 2. Interview with testing personnel (staff C) on November 3, 2021 at 10:15 AM confirmed the technical consultant did not document the evaluation of the performance of microscopic evaluations for staff A and B.